

REMARKS**1. Formal Matters****a. Status of the claims**

Reconsideration and allowance of the present application based on the foregoing amendments and following remarks are respectfully requested. Claims 21-29 are pending in the application. Claim 22 is allowed; claims 32-36 are new; and claims 24-31 are hereby canceled without prejudice to pursuing the claimed subject matter in a continuing application. Upon entry of these amendments, claims 21-23, and 32-36 are pending and under active consideration. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present application.

b. Amendments to the claims

Previous claim 21 was related to nucleic acid of 18 to 120 nucleotides comprising SEQ ID NO: 863, which is a hairpin comprising the miRNA as set forth in SEQ ID NO: 3588. For the convenience of the Examiner, an alignment of the hairpin and the miRNA is shown below.

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TTCCCATAGCCTGTCTAACTAGCCTTCCCGTGAGAGTTTATGAACATGTATCTCACCAGAATGCTAGTTTGTAGAGGCTATGCGGGA  SEQ ID NO: 386
                                     TCACCAGAATGCTAGTTTGTAGAG                               SEQ ID NO: 3588

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Claim 21 is amended to recite in part an isolated nucleic acid consisting of 24 to 120 nucleotides, wherein the sequence of the nucleic acid comprises SEQ ID NO: 3588, support for which can be found at claim 1 as originally filed. SEQ ID NO: 3588 is 24 nucleotides in length, and original claim 1 recites, "RNA precursor is about 50 to about 120 nucleotides in length..."

Part (c) of claim 21 is amended to recite a sequence at least 70.9% identical to parts (a) or (b), support for which may be found in Tables 1 and 2 of the application as originally filed. Table 1 discloses that precursor RNA (hairpin) GAM877 has the sequence as set forth in SEQ ID NO: 863 and contains the miRNA as set forth in SEQ ID NO: 3588, as follows:

GENE	PRECURSOR-SEQUENCE	P-SEQID	GENE-SEQ	G-SEQID	FOLDED PRECURSOR
GAM877	TTCCCATAGCCTGTCTAACT AGCCTTCCCGTGAGAGTTTA TGAACATGTATCTCACCAGA ATGCTAGTTTGTAGAGGCTA TGCGGGA	863	TCACCAGAAT GCTAGTTTGT AGAG	3588	<pre> - GTCT- C CC GTT G TTCC CATAGCCT AACTAGC TTC GTGAGA TAT A AGGG GTATCGGA TTGATCG AAG CACTCT GTA A C GAIGT T AC AT- C </pre>

Table 2 discloses that 17 out of 24 nucleotides (70.9%) of SEQ ID NO: 3588 are sufficient to target the binding site of OPHN1 (SEQ ID NO: 8403), as shown below:

GENE	TARGET	UTR	SEQUENCE	SEQID	BINDING-SITE
GAM877	OPHN1	3'	CTCTACAAATTTTCTGTGGTG A	8403	GAATGCT TCACCA AGTTTGTAGAG AGTGGT TTAACATCTC GTCTTT_

Claim 23 is amended to recite in part an isolated nucleic acid consisting of a nucleotide sequence of SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588. Support for amended claim 23 can be found as described above for amended claim 21.

New claims 32 and 33 relate to a nucleic acid of claim 21 or 23, respectively, wherein part (c) is a sequence at least 79.2% identical to (a) or (b), support for which can be found at Table 2 as originally filed. Table 2 discloses that 19 out of 24 nucleotides (79.2%) of the miRNA related to SEQ ID NO: 3588 are sufficient to target the binding site of LOC144699 as follows:

GAM877	LOC144699	3'	CTCTGCGCCTCCGGCACTCTGG TGA	37769	A AGTT_ TCACCAGA TGCT TGTAGAG AGTGGTCT ACGG GCGTCTC C CCTCC
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New claims 34 and 35 relate to a nucleic acid of claim 21 or 23, respectively, wherein (c) is a sequence at least 83.4% identical to (a) or (b), support for which can be found a Table 2 as originally filed. Table 2 discloses that 20 out of 24 nucleotides (83.4%) of the miRNA related to SEQ ID NO: 3588 are sufficient to target the binding site of HARSL as follows:

GAM877	HARSL	3'	CTACGGAACCAGATTCTGGTGA	14509	G A _ TCACCAGAAT CT GTTT GTAG AGTGGTCTTA GA CAAG CATC _ C G
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New claim 36 recites a vector comprising the nucleic acid of any one of claims 21-23 and 32-35, support for which can be found at paragraph 0024 of the specification as originally filed, which recites in part "the invention includes a vector including the DNA."

2. Patentability Remarks

a. 35 U.S.C. § 102(b) rejection over Cronin et al.

On page 3 of the Office Action, the Examiner rejects claims 21, 23, 24, and 29 under 35 U.S.C. § 102(b) as allegedly being anticipated by Cronin et al. (U.S. Pat. No. 6,027,880) ("Cronin" hereafter). The Examiner asserts that Cronin teaches SEQ ID NOs: 11, 33, 49, and 107, which all have 14 out of 18 nucleotides identical to 18 consecutive nucleotides SEQ ID NO: 863 (an alleged 77.7% identity), thereby allegedly meeting the structural limitations in the claims.

Applicant respectfully disagrees in view of the amendment to the claims. For the Examiner's convenience, an alignment is presented below of instant SEQ ID NO: 863 (hairpin) and SEQ ID NO: 3588 (miRNA) with SEQ ID NOS: 11, 33, 49, and 107 of Cronin.¹

	1	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85
SEQ ID NO: 863	TTCCCATAGCCTGTCTAACTAGCCTTCCCGTGAGAGTTTATGAACATGTATCTCACCAGAATGCTAGTTTGTAGAGGCTATGCGGGA																	
SEQ ID NO: 3588	TCACCAGAATGCTAGTTTGTAGAG																	
CRONIN SEQ ID NO: 11	XXXXTCCCGTGAGAGGTTA (0/18 = 0%)																	
CRONIN SEQ ID NO: 33	XXXXTCCCGTGAGAGGTTA (0/18 = 0%)																	
CRONIN SEQ ID NO: 49	XXXXTCCCGTGAGAGGTTA (0/18 = 0%)																	
CRONIN SEQ ID NO: 107	XXXXTCCCGTGAGAGGTTA (0/18 = 0%)																	

Applicant respectfully submits that amended claim 21 recites a nucleic acid consisting of 24 to 120 nucleotides wherein the sequence of the nucleic acid comprises SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588. Applicant submits that, as shown above, SEQ ID NOS: 11, 33, 49, and 107 of Cronin do not overlap with SEQ ID NO: 3588. Each Cronin sequence aligns with nucleotides 22 to 39 of instant SEQ ID NO: 863. In addition, SEQ ID NOS: 11, 33, 49 and 107 fail to meet the amended length limitation of 24 to 120 nucleotides. Accordingly, Cronin does not teach a nucleic acid that is 70.9% identical to SEQ ID NO: 3588.

Similarly, claim 23 recites in part a nucleic acid consisting of a sequence at least 70.9% identical to SEQ ID NO: 3588. Cronin fails to teach or suggest any sequence that is set forth in SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588.

In view of the foregoing, Cronin neither teaches nor suggests all the limitations of amended claims 21 and 23. Applicant notes that claims 24 and 29 are canceled without prejudice, and that new claims 32-36 draw their dependency from claim 21 or 23, and therefore are not anticipated by Cronin. In view of the foregoing amendment and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 21, 23, 24, and 29 under 35 U.S.C. § 102(b) over Cronin, and a similar rejection of new claims 32-36 would be improper.

b. 35 U.S.C. § 102(b) over Vider et al.

On page 3 of the Office Action, the Examiner rejects claims 21, 23, 24, and 29 under 35 U.S.C. § 102(b) as allegedly being anticipated by Vider et al. (WO 99/34016) ("Vider" hereafter). The Examiner asserts that Vider teaches an isolated nucleic acid A9(+) which is 18/21, or 85.7% identical to at least 18 consecutive nucleotides of SEQ ID NO: 863, thereby allegedly meeting the structural requirements set forth in the claims.

¹ Please note that the alignments provided by the Examiner did not show the entire disclosed sequence of Cronin. Applicant has arbitrarily placed the letter X on the 5' end of the alleged cited sequence to indicate the true length of the nucleic acid.

Applicant respectfully disagrees with the Examiner's characterization of the cited nucleic acid of Vider. The Applicant submits that only 17 nucleotides, rather than 18 nucleotides, of the 21 nucleotide A9(+) sequence of Vider are identical to SEQ ID NO: 863. For purposes of this reply, Applicant will assume the nucleic acid of Vider is allegedly 81.0% identical rather than 85.7% identical to SEQ ID NO: 863. Applicant respectfully request clarification if this interpretation is erroneous.

For the Examiner's convenience, an alignment is presented below of SEQ ID NO: 863 (hairpin) and SEQ ID NO: 3588 (miRNA) of the instant application with SEQ ID NOS: A9+ of Vider.

	1	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85
SEQ ID NO: 863	TTC CATAGCCTGCTCTAACTAGCCTTCCCGTGAGAGTTTATGAACATGTATCTCACCAGAATGCTAGTTTGTAGAGGCTATGCGGGA																	
SEQ ID NO: 3588	TCACCAGAATGCTAGTTTGTAGAG																	
VIDER A9(+)	XXTCAACATGTACC (7/21 = 33.0%)																	

As shown above, the sequence alignment between the relevant cited nucleotides of Vider's A9(+) sequence and of SEQ ID NO: 3588 indicates that only 7 out of 21 nucleotides of Vider's A9(+) sequence, or 33.0%, are identical to instant SEQ ID NO: 3588. In addition, Vider's A9(+) sequence fails to meet the amended length limitation of 24 to 120 nucleotides. Accordingly, Vider fails to teach or suggest a sequence comprising SEQ ID NO:3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588.

With regards to claim 23, Vider fails to teach or suggest a nucleic acid consisting of a sequence as set forth in SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588. Accordingly, Vider fails to teach or suggest all the limitations of independent claims 21 and 23. As discussed above, claims 24 and 29 are canceled without prejudice, and new claims 32-36 are not anticipated by Vider because these claims draw their dependency from claim 21 or 23. In view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 21, 23, 24, and 29 under 35 U.S.C. § 102(b) over Vider, and a similar rejection of new claims 32-36 would be improper.

c. 35 U.S.C. § 102(b) over Lutz

On page 4 of the Office Action, the Examiner rejects claims 21, 23, 24, and 29 under 35 U.S.C. § 102(b) as allegedly being anticipated by Lutz (EP 1013775) ("Lutz" hereafter). The Examiner asserts that Lutz teaches a 25-mer as set forth in SEQ ID NO: 64 that is 18/25, or 85.7% identical to SEQ ID NO 863, thereby allegedly meeting the structural requirements set forth in the claims.

Applicant respectfully disagrees with the Examiner's characterization of the cited nucleic acid of Lutz. Applicant respectfully submits that if SEQ ID NO: 64 of Lutz shares 18 out of 25 nucleotides with SEQ ID NO: 863, the nucleic acid of Lutz is 72% identical to SEQ ID NO: 863 rather than the asserted 85.7%. For purposes of this reply, Applicant will assume the nucleic acid of Lutz is allegedly 72.0%

For the Examiner's convenience, an alignment is presented below of SEQ ID NO: 863 (hairpin) and SEQ ID NO: 3588 (miRNA) of the instant application with SEQ ID NO: 64 of Lutz.

Applicant submits that only 16 out of 25 nucleotides or 64.0% are identical over a region of overlap between SEQ ID NO: 64 of Lutz and the nucleotides of SEQ ID NO: 3588. Applicant respectfully submits that, given the limitations of amended claim 21 described above, Lutz does not teach or suggest a nucleic acid comprising SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588.

With regards to claim 23, Lutz fails to teach or suggest a nucleic acid consisting of a sequence as set forth in SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588. Accordingly, Lutz does not teach or suggest all the limitations of claims 21 and 23. New claims 32-36 draw their dependency from claims 21 or 23, and are therefore not anticipated by Lutz. In view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 21, 23, 24, and 29 under 35 U.S.C. § 102(b) over Lutz, and a similar rejection of claims 32-36 would be improper.

On pages 4 and 5 of the Office Action, the Examiner rejects claims 21, 23-27 and 29 under 35 U.S.C. § 102(e) as allegedly being anticipated by Freier et al. (U.S. Pat. No. 6,503,756) (“Freier” hereafter). The Examiner asserts that Freier teaches SEQ ID NO: 131, which is 16/20, or 80.0% complementary to SEQ ID NO: 863, and thereby falls within the scope of the claimed subject matter.

For the Examiner's convenience, an alignment is presented below of SEQ ID NO: 863 (hairpin) and SEQ ID NO: 3588 (miRNA) of the instant application with SEQ ID NO: 131 of Freier.

In view of the foregoing amendments, Applicant respectfully submits that only 10 out of 20 nucleotides (50%) over a region of overlap between SEQ ID NO: 131 of Freier and instant SEQ ID NO: 3588. In addition, Freier's sequence fails to meet the amended length limitation of 24 to 120 nucleotides. Accordingly, Freier does not teach or suggest a sequence of claim 21 as set forth in SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588.

With regards to claim 23, Freier fails to teach or suggest a nucleic acid consisting of a sequence as set forth in SEQ ID NO: 3588 or a sequence at least 70.9% identical to SEQ ID NO: 3588.

Accordingly, Freier fails to teach all the limitations of claims 21 and 23. As discussed above, claims 32-36 draw their dependency from claim 21 or 23 and therefore are not anticipated by Freier. In view of foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 21, 23-27 and 29 under 35 U.S.C. § 102(e) over Freier, and a similar rejection of claims 32-36 would be improper.

e. 35 U.S.C. § 103(a)

On pages 5 and 6, the Examiner rejects claim 28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Freier in view of Monte et al. The Examiner asserts that Freier teaches an isolated nucleic acid that is 80.0% complementary to SEQ ID NO: 863, and that Monte teaches a vector comprising an antisense HCMV gene. The Examiner further asserts that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Freier and Monte to make a vector comprising the nucleic acid of Freier. In view of the foregoing amendment, the Applicant respectfully disagrees.

Specifically, claim 28 is canceled without prejudice, but new claim 36 is directed to a vector comprising the nucleic acids of claims 21-23, and 32-35. Applicant submits that a *prima facie* case of obviousness requires that all the claim limitations must be taught or suggested (see M.P.E.P. 2143.03). Applicant notes that new claim 36 depends (in part) from claim 21 and therefore must be construed to include all the limitations of claim 21 (see M.P.E.P. 608.01(n)). For reasons described above, Applicant submits that Freier does not teach or suggest the nucleic acids of amended claim 21. Applicant also submits a *prima facie* case of obviousness would be improper for new claim 36 because Freier in combination with Monte does not teach all of the limitations of claim 21. Accordingly, Applicant submits that the rejection of claim 28 is moot, and a similar rejection of new claim 36 is not applicable.

3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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